APR 20 2005

We are **smith&nephew**

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

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K050580

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew InteliJET™ Fluid Management Systems

Date Prepared: March 2, 2005

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Kathleen Burns
Regulatory Affairs Associate
Phone: (978) 474-6301
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew InteliJET™ Fluid Management Systems
Common Name:	Arthroscopic Fluid Management System
Classification Name:	Arthroscopes

D. Predicate Devices

The Smith & Nephew InteliJET™ Fluid Management Systems are substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K002040: FMS SOLO, Future Medical Systems
K033927: Arthroscopic Pump A115, World of Medicine
K041824: NeXtra™ Arthroscopic Pump and Shaver System

E. Description of Device

The Smith & Nephew InteliJET™ Fluid Management Systems are microprocessor-based systems designed for controlled delivery of irrigation fluid during intra-articular surgery. This controlled delivery is accomplished via an electronic pressure control loop between the control unit and the tube cassette.

F. Intended Use

The Smith & Nephew InteliJET™ Fluid Management Systems are indicated for use during arthroscopic joint surgery to regulate flow of irrigation fluids in the knee, shoulder, hip and small joints to maintain intra-articular pressure for uniform distension and clear visualization of the surgical site.

G. Comparison of Technological Characteristics

The Smith & Nephew InteliJET™ Fluid Management Systems have the same technological characteristics as the predicate devices, the Arthroscopic Pump A115, FMS SOLO, and NeXtra™ Arthroscopic Pump and Shaver System. In addition, both the Smith & Nephew InteliJET™ Fluid Management System and predicate device are intended for use during arthroscopic joint surgery to regulate flow of irrigation fluids in the knee, shoulder, hip and small joints.

H. Summary Performance Data

All verification and validation data demonstrate that the devices are safe and effective and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2005

Ms. Kathleen Burns
Regulatory Affairs Associate
Smith and Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K050580
Trade/Device Name: Smith and Nephew InteliJET™ Fluid Management System
Smith and Nephew InteliJET™ Fluid Management System-HERMES Ready
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 4, 2005
Received: March 7, 2005

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050580

Indications for Use

510(k) Number (if known): ______________________

Device Name: Smith & Nephew InteliJET™ Fluid Management System

Indications For Use:

The Smith & Nephew InteliJET™ Fluid Management System is indicated for use during arthroscopic joint surgery to regulate flow of irrigation fluids in the knee, shoulder, hip and small joints to maintain intra-articular pressure for uniform distension and clear visualization of the surgical site.

Device Name: Smith & Nephew InteliJET™ Fluid Management System-HERMES Ready

Indications For Use:

The Smith & Nephew InteliJET™ Fluid Management System-HERMES Ready is indicated for use during arthroscopic joint surgery to regulate flow of irrigation fluids in the knee, shoulder, hip and small joints to maintain intra-articular pressure for uniform distension and clear visualization of the surgical site.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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